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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/707,320

11/07/2000

Susan B. Sobolov-Jaynes

PC10408A

9424

7590

09/24/2002

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EXAMINER

JARVIS, WILLIAM R A

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 09/24/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/707,320

Applicant(s)

SOBOLOV-JAYNES, SUSAN B.

Examiner

William R. Jarvis

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- ☐ Interview Summary (PTO-413) Paper No(s). _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

Art Unit: 1614

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1-16 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-35 of copending Application No. 09/867,079 and claims 1-33 of copending Application No. 09/867,357. Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions claim the combination of the same NK-1 antagonists in combination of an anxiolytic/antidepressant.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's remarks regarding the obviousness double-patenting rejection filed July 2, 2002 have been carefully considered, but are not persuasive. Although copending application no. 09/867,079 discloses NK-3 antagonists and copending application no. 09/867,357 discloses 5-HT1D antagonists, the fact that these class of compounds are known to exhibit antidepressant and/or /anxiolytic activity makes the claims of the present invention obvious to one skilled in the art. Since the claims of the present invention require the combination of any anxiolytic agent or antidepressant (which includes the NK-3 and 5-HT1D antagonists of the copending applications) with the same NK-1 antagonists of the copending application, the claims are clearly obvious to one of ordinary skill in the art. Accordingly, this double-patenting rejection is proper.

3. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,773,450 (Lowe, III et al) in view of The Merck Index. Lowe discloses pharmaceutical compositions of applicant's elected specie CP 122721 useful in the treatment of anxiety and depression; see col. 6, lines 35 and 36 and col. 8, lines 18 and 38. Applicant's claims differ in that

Art Unit: 1614

they additionally require (a) an anxiolytic agent or an antidepressant. However, The Merck Index teaches that applicant's elected specie sertraline is an antidepressant. It would have been obvious to one of ordinary skill in the art to combine the elected species CP 122721 and sertraline in one composition since each compound is known to exhibit the same therapeutic effect, i.e. treatment of depression. See *In re Kerkhoven* 205 USPQ 1069. The claimed amounts are obvious since it is within the skill of the artisan to determine the amount of drug that provides the therapeutic effect required by the patient while minimizing adverse side effects.

Applicant's remarks regarding the obviousness rejection filed July 2, 2002 have been carefully considered, but are not persuasive. Although the prior art references do not individually disclose the combination of the elected NK-1 antagonist CP 122721 with sertraline, the fact that each compound is known to exhibit antidepressant activity provides motivation for one skilled in the art to combine the two compounds in one composition (e.g. for treatment of depression). See *In re Kerkhoven* 205 USPQ 1069, which is well-established case law related to this situation. However, this rejection may be overcome by a demonstration of unexpected results (e.g. a showing of synergistic effects of the combination of NK-1 antagonists with various anxiolytic and/or antidepressants). This evidence should be presented in the form of a declaration and should be commensurate in scope with the claimed invention.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

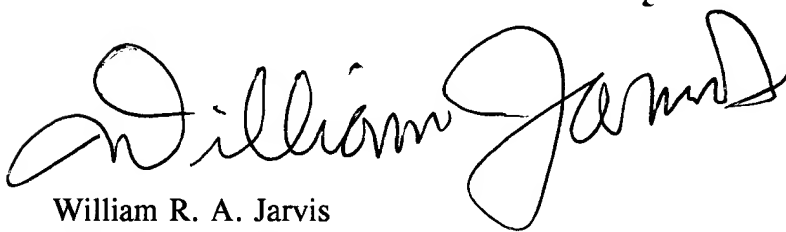
Art Unit: 1614

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William R. A. Jarvis whose telephone number is (703) 308-4613.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne C. Seidel, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

A handwritten signature in black ink, reading "William Jarvis". The signature is stylized with a large, looping "W" and a cursive "Jarvis".

William R. A. Jarvis
Primary Examiner
Art Unit 1614
September 22, 2002